Remarks/Arguments

Claims 50-52, 54-75, 77-95, 97-104 and 107-131 are pending. Claims have been amended to recite "at least two matrix-forming agents." Support for this amendment can be found on page 6, lines 32-33, page 7, line 1-15, and page 8, lines 23-35. Claims 55, 78, and 107 have been canceled, as their recitation of disintegration time less than 2 minutes has been incorporated into claims 50, 73, and 97.

112 Rejections

Claims 50-52, 54-75, 77-95, 97-104 and 107-131 have been rejected as being indefinite for the recitation of "at least two rapidly dispersible matrix forming bulking/releasing agents, or a combination of a matrix forming bulking agent and a matrix-forming releasing agent." This has been amended to recite "at least two matrix-forming agents." The matrix-forming agent is the agent which both "provides a mass in which the particles of drug are embedded or retained" (page 6, lines 32-33) and which "must dissolve or disperse upon contact with an aqueous environment and release the phospholipid coated therapeutic agent particle" (page 8, lines 23-35). The specification explicitly describes a variety of suitable matrix-forming agents (page 7, lines 1-15). Accordingly, Applicants submit that the amendment to "at least two matrix-forming agents" renders the claim definite, so that the 112 rejection has been overcome

103 Rejections

Claims 50-52, 54-75, 77-95, 97-104 and 107-131 were rejected under 35 U.S.C. §103(a) as obvious over WO 98/07414 in combination with Green (5,976,577) or Venkatesh (6,475,510). The Examiner's position is that WO 98/07414 discloses the same elements of the claimed process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds except for the additional step of adding rapidly dispersible matrix-forming agents, and that Green and Venkatesh disclose rapidly dispersible matrix-forming agents. Applicants traverse this rejection.

The present invention is directed to an **improvement** in the dispersibility of micronized particles through the specific selection of excipients. Specification at page 3, lines 29-31. Micronized particles as disclosed in WO 98/07414 "are required in the practice of the present

invention." Id. at page 4, line 2. The micro particles with phospholipid surfactants adsorbed thereto as disclosed by WO 98/07414 are but a starting point for the present invention. The essence of the present invention is the steps which follow the production of the micro particle suspension - admixing this suspension with "surface modifying agent(s) and/or matrix-forming agent(s) which are present in an amount sufficient to allow freeze-drying and subsequent release of the surface coated drug particles upon contact with an aqueous environment." Id. at page 4, lines 14-17.

The invention disclosed by WO 98/07414 is a process of making non-aggregating, submicron sized primary micro particles and the particles so produced. WO 98/07414 is concerned with suspensions, the constituent particles of which are stable to the Ostwald Ripening process and so maintain their small particle size. All of the exemplified formulations are suspensions in aqueous media. Whereas WO 98/07414 does suggest that the suspensions can be dried and formed into capsules or tablets, nothing is mentioned regarding the properties of these capsules or tablets when exposed to aqueous media. The present invention on the other hand is concerned with an entirely different problem: the provision of solid oral dosage forms that disintegrate rapidly upon contact with aqueous media. Rapid dispersion or disintegration is a term used to characterize the presently claimed invention and this term is not contemplated by WO 98/07414. As currently amended, all claims require that the disintegration time of the solid dosage form is less than 2 minutes. Such a rapid disintegration time was not taught or even suggested by WO 98/07414.

Nowhere in WO 98/07414 is there a teaching that at least two, rapidly dispersible, matrix-forming agents are mixed with the micro particles disclosed by WO 98/07414. Nowhere in WO 98/07414 is there a teaching of a process that includes the formation of a solid support matrix wherein fenofibrate-containing particles are dispersed and embedded throughout, and also wherein this support matrix dissolves or disperses in a rapid disintegration time of less than 2 minutes when the solid matrix contacts an aqueous environment. The foregoing teachings are newly provided to the art by Applicants and are not found in WO 98/07414.

Green and Venkatesh address a different problem than that addressed by WO 98/07414, so that one skilled in the art would not combine the teachings. Green and Venkatesh both

address the problem of masking an unacceptable taste for a pharmaceutical compound. This problem is not addressed by WO 98/07414. Additionally, Venkatesh discloses a combination of only dry granules, whereas the present claims first prepare an aqueous solution. Nowhere in Venkatesh is taught preparation of an aqueous solution. Additionally, the particles taught by Green are much larger than those claimed herein. As disclosed in Green, the particles are generally 75-400 um, more preferably 100-300 um. See col. 3, lines 15-20. As claimed herein, the particles in suspension are between 0.05-10 um. Accordingly, WO 98/07414 in combination with Green and Venkatesh fail to make obvious Applicants' invention as presently claimed. Withdrawal of the rejection is thus respectfully requested.

Double Patenting

Claims 50-52, 54-75, 77-95, 97-104 and 107-131 were rejected under obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,922,355. Claims 50-52, 54-75, 77-95, 97-104 and 107-131 were rejected under the obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,228,399. Claims 50-52, 54-75, 77-95, 97-104 and 107-131 were rejected under obviousness-type double patenting over claims 1-22 of U.S. Patent No. 6,465,016. Claims 50-52, 54-75, 77-95, 97-104 and 107-131 were provisionally rejected under the obviousness-type double patenting over claims 1, 2, 4-25, 45-47, 52, 53, 55, 56, 65 and 101-119 of co-pending application U.S. Serial No. 10/260,788. Applicants postpone the filing of a terminal disclaimer until the claims have otherwise reached allowance.

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. With the enclosed three month extension of time, this response is due on or before December 27, 2006. The Commissioner is hereby authorized to charge payment of any fees that may be required, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 28069-546.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529
Naomi S. Biswas, Reg. No. 38,384
Attorneys for Applicants
MINTZ, LEVIN
Tel: 617-542-6000
Fax: 617-542-2241
Customer No. 30623

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